CLAIMS

1. An inflatable balloon structure for catheters, such as a catheter for angioplasty or for depositing an endolumenal prosthesis or stent in a duct, for example, a vascular duct,

the balloon structure being of predominant longitudinal extent with a proximal end and a distal end, and being suitable for performing an expansion in an object to be dilated,

the balloon structure comprising a wall which has, transverse the longitudinal extent, at any point, an annular cross-section delimited externally by an outer surface which, at least in an intermediate portion thereof, is suitable for coming into contact with the object to be dilated, and internally by an inner surface which delimits an inflation chamber, in which:

at least one wall cavity is provided in the wall and is formed within the annular cross-section which delimits the inflation chamber so as to be disposed between the outer surface and the inner surface

the cavity extending, without interruptions and/or

openings, longitudinally relative to the balloon structure between the proximal end and the distal end so that, when the balloon structure is inflated or expanded, the outer surface of the intermediate portion has, in cross-section transverse the longitudinal extent of the balloon structure, uniform curvature around the entire annular extent of the cross-section.

2. A balloon structure according to Claim 1 in which, when the balloon structure is inflated or expanded, the outer surface of the intermediate portion is free of protuberances or recesses.

3. A balloon structure according to any one of Claims 1 to 2 in which the wall cavity is within the wall which delimits the inflation chamber for the whole of its extent which affects the balloon structure.

4. A balloon structure according to any one of Claims 1 to 3 in which, when the balloon structure is inflated or expanded, the outer surface of the intermediate portion is cylindrical.

5. A balloon structure according to any one of Claims 1 to 4 in which, when the inflation chamber is expanded,

the balloon structure has an annular cross-section of the outer surface, transverse the longitudinal extent of the balloon structure.

6. A balloon structure according to any one of Claims 1 to 5 in which, when the inflation chamber is expanded, the balloon structure has a substantially circular cross-section of the outer surface, transverse the longitudinal extent of the balloon structure.

7. A balloon structure according to any one of Claims 1 to 6 in which the balloon comprises a proximal tubular portion in the vicinity of the proximal end.

8. A balloon structure according to any one of Claims 1 to 7 in which the balloon comprises a proximal shank connecting the proximal tubular portion and an intermediate portion.

9. A balloon structure according to Claim 8, in which the proximal shank has an internal taper angle of between 20 degrees and 40 degrees, preferably of 30 degrees.

10. A balloon structure according to any one of Claims 1 to 9 in which the balloon comprises a distal connecting

shank between the intermediate portion and a portion for connection to a distal catheter tip.

11. A balloon structure according to Claim 10, in which the distal shank has an internal taper angle of between 20 degrees and 40 degrees, preferably of 30 degrees.

12. A balloon structure according to any one of Claims 1 to 11, in which the wall cavity is separated from the inflation chamber by an internal portion of the wall.

13. A balloon structure according to any one of Claims 1 to 12, in which the cavity is separated from the outer surface by an external portion of the wall.

14. A balloon structure according to any one of Claims 1 to 13, in which, when the balloon structure is inflated or expanded, the inner surface of the intermediate portion is smoothed, rounded, or free of sharp corners.

15. A balloon structure according to any one of Claims 1 to 14, in which, when the balloon structure is inflated or expanded, the inner surface of the intermediate portion has an annular cross-section, transverse the longitudinal extent of the balloon.

16. A balloon structure according to any one of Claims 1 to 15, in which the structure is produced from an extruded tube having at least two cavities, one of which is deformed to form the inflation chamber of the balloon structure.

17. A balloon structure according to Claim 16, in which, prior to the deformation of a cavity of the extruded tube to form an inflation chamber, the extruded tube has an at least partially flat partition separating the at least two cavities.

18. A balloon structure according to any one of Claims 16 to 17, in which, prior to the deformation of a cavity of the extruded tube to form an inflation chamber, the extruded tube has a partition separating the at least two cavities, which partition has, in cross-section transverse the extruded tube, a minimum thickness of between 55% and 100% of the minimum thickness of the wall portion which separates one of the cavities from the outer surface.

19. A balloon structure according to any one of Claims 16 to 18, in which, prior to the deformation of a cavity of

the extruded tube to form an inflation chamber, the extruded tube has a partition separating the at least two cavities which partition has, in cross-section transverse the extruded tube, a minimum thickness of between 60% and 70% of the minimum thickness of the wall portion which separates one of the cavities from the outer surface.

20. A balloon structure according to any one of Claims 1 to 19, in which the balloon structure is produced by the expansion of an inflation cavity of a tube with at least two cavities, the tube being produced by coextrusion of at least two materials, a first of these materials forming the wall or wall portion which delimits the inflation cavity.

21. A balloon structure according to Claim 20, in which the material which delimits the inflation cavity is a material that is semi-compliant or partially yielding but resistant to the maximum balloon-inflation pressure.

22. A balloon structure according to any one of Claims 1 to 21, in which the balloon structure is produced by the expansion of an inflation cavity of a tube with at least two cavities, the tube being produced by coextrusion of at least two materials, a second of these materials

forming at least a part of the wall portion which delimits a wall cavity.

23. A balloon structure according to Claim 22, in which the second material forms the wall portion which separates the wall cavity from the outer surface.

24. A balloon structure according to any one of Claims 22 to 23, in which the second material has a greater flexibility than the first material.

25. A balloon structure according to any one of Claims 1 to 24, in which the wall cavity is coated with or delimited by a layer of material with a coefficient of friction such as to facilitate the sliding of a guide wire housed in the wall cavity.

26. A balloon structure according to any one of Claims 1 to 25, in which the balloon structure is produced by the expansion of an inflation cavity of a tube with at least two cavities, the tube being produced by coextrusion of three materials.

27. A balloon structure according to any one of Claims 1 to 26, in which, when the balloon structure is inflated

or expanded, the wall cavity is separated from the inflation chamber by a wall portion which has, in cross-section transverse the longitudinal extent of the balloon, a thickness of between 55% and 100% of the thickness of a wall portion which separates the wall cavity from the outer surface.

28. A balloon structure according to any one of Claims 1 to 27, in which, when the balloon structure is inflated or expanded, the wall cavity is separated from the inflation chamber by a wall portion which has, in cross-section transverse the longitudinal extent of the balloon, a thickness of between 60% and 70% of the thickness of a wall portion which separates the wall cavity from the outer surface.

29. A balloon structure according to any one of Claims 1 to 28, in which the inflation chamber is closed in a leaktight manner onto an apex tip, leaving solely openings for access to one or more guide-wire cavities.

30. An inflatable balloon structure for catheters, such as a catheter for angioplasty or for depositing an endolumenal prosthesis or stent in a duct, for example, a vascular duct, the balloon structure being of predominant

longitudinal extent with a proximal end and a distal end and being suitable for performing an expansion in an object to be dilated, the balloon structure comprising a wall which has, transverse the longitudinal extent, at any point, an annular cross-section delimited externally by an outer surface which, at least in an intermediate portion, is suitable for coming into contact with the object to be dilated, and internally by an inner surface which delimits an inflation chamber, in which at least one wall cavity is provided in the wall and is formed within the annular cross-section which delimits the inflation chamber, so as to be disposed between the outer surface and the inner surface,. the cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the proximal end and the distal end.

31. A method of producing a balloon structure according to any one of Claims 1 to 30, which provides for the steps of:

- providing a tubular duct of predominant longitudinal extent, provided with at least two cavities which extend along its entire longitudinal extent whilst remaining separate from one another, between proximal openings and

distal openings,

- inserting at least a portion of the duct in a die provided with a cavity that is widened to form the desired shape of the expanded balloon,

- closing in a leaktight manner one of the distal and proximal openings, or sections of the duct outside the die, of at least one cavity to be expanded,

- heating the portion of duct that is disposed in the die to a temperature which permits permanent deformation of the material or of one of the materials which constitute the tubular duct, at least in the region of the cavity to be expanded,

- admitting fluid under pressure to the cavity to be expanded so as to deform the wall of the duct which delimits the cavity, causing the wall to fit against the walls of the widened cavity delimited by the die, the second cavity remaining incorporated in the wall thus deformed.

32. A method according to Claim 31, in which, before the admission of fluid under pressure to one of the cavities,

a stylet is inserted in the other cavity so as to prevent the deformation of the heated wall from obstructing this other cavity.

33. A method according to Claim 32, in which the stylet is coated with non-stick material such as, for example, Teflon(TM).

34. A balloon catheter comprising a balloon structure as defined in any one of Claims 1 to 33.

35. A catheter according to Claim 34, which includes an apex tip which has a proximal end and an apex end and comprises:

a tubular apex portion disposed in the vicinity of the apex end, and

a proximal connecting tube disposed in the vicinity of the proximal end, in which:

the proximal connecting tube is partially housed with a distal portion thereof inside a proximal portion of the apex tube,

the connecting tube being connected to the apex tube so as to form a cavity which extends without interruption from an opening disposed at the proximal end of the connecting tube to an opening disposed at the apex end of the apex tube,

the connecting tube being suitable for connection to a wall cavity suitable for housing a guide wire, the wall cavity being provided within a wall which delimits a balloon inflation chamber.

36. A catheter according to Claim 34, including an apex tip which has a proximal end and an apex end and comprises:

a tubular apex portion disposed in the vicinity of the apex end,

a proximal connecting tube disposed in the vicinity of the proximal end, and

a tube for anchoring a thrust wire or rod, also disposed in the vicinity of the proximal end, in which:

the anchoring tube and the proximal connecting tube are

arranged at least partially side by side and are housed with respective distal portions inside a proximal portion of the apex tube,

the connecting tube being connected to the apex tube so as to form a cavity which extends without interruption from an opening disposed at the proximal end of the connecting tube to an opening disposed at the apex end of the apex tube,

the connecting tube being suitable for connection to a wall cavity suitable for housing a guide wire, the wall cavity being provided within a wall which delimits a balloon inflation chamber,

the anchoring tube being suitable for connection to a distal opening of a balloon structure for the leaktight closure thereof and for the anchorage of a distal end of a thrust wire provided inside the balloon.

37. A catheter according to Claim 36 in which the anchoring tube, the connecting tube, and the apex tube are welded to form a single body.

38. A catheter according to Claim 34 including an apex

tip which has a proximal end and an apex end and comprises:

a tubular apex portion disposed in the vicinity of the apex end,

a first proximal connecting tube disposed in the vicinity of the proximal end, and

a second connecting tube, also disposed in the vicinity of the proximal end, in which:

the first connecting tube and the second connecting tube are arranged at least partially side by side and are housed with respective distal portions inside a proximal portion of the apex tube,

the first and second connecting tubes being connected to the apex tube so as to form cavities which extend without interruption from respective openings disposed at the proximal ends of the connecting tubes to at least one opening disposed at the apex end of the apex tube,

the first connecting tube being suitable for connection to a wall cavity suitable for housing a guide wire, the

wall cavity being provided within a wall which delimits a balloon inflation chamber,

the second connecting tube being suitable for connection to a guide-wire duct suitable for housing a guide wire, the guide-wire duct being disposed within the balloon structure.

39. A catheter according to Claim 38, in which the first and second connecting tubes and the apex tube are welded to form a single body.

40. A catheter according to any one of Claims 24 to 39, in which the thrust wire is disposed inside the catheter shaft connected proximally to the balloon.

41. A catheter according to any one of Claims 34 to 40, in which the guide-wire duct is disposed inside the catheter shaft which is connected proximally to the balloon.

42. A catheter according to any one of Claims 34 to 41, in which the wall portion which separates the wall cavity from the outer surface has an opening which forms a lateral aperture for allowing a guide wire to be inserted

in the wall cavity or to emerge therefrom.

43. A catheter according to any one of Claims 34 to 42, in which the balloon structure is connected proximally to a shaft comprising an inflation cavity connected to the inflation chamber in a leaktight manner for the flow of a fluid from the shaft to the inflation chamber and vice versa.

44. A catheter according to any one of Claims 34 to 43, in which the balloon structure is connected proximally to a shaft comprising a guide-wire cavity connected to the wall cavity in a leaktight manner for the passage of a guide wire.

45. A catheter according to Claim 44, in which the guide-wire cavity is disposed in the wall of the shaft and is separated from the outer surface of the shaft by a wall portion.

46. A catheter according to Claim 45, in which the shaft has an opening in the wall portion which separates the guide-wire cavity from the outer surface, the opening being suitable for the passage of a guide wire.

47. A catheter according to any one of Claims 34 to 46, in which the balloon structure is connected proximally to a shaft comprising a guide-wire cavity connected to the wall cavity in a leaktight manner for the passage of a guide wire, the guide-wire cavity being provided in a guide-wire duct provided inside the shaft.

48. A catheter according to Claim 47, in which the duct is connected in a leaktight manner to a lateral opening provided in the outer wall of the shaft to allow a guide wire to be inserted in the guide-wire cavity of the guide-wire duct or to emerge therefrom.

49. A catheter according to any one of Claims 34 to 48, in which the shaft has a plurality of portions formed with a plurality of ducts.

50. A catheter according to any one of Claims 34 to 49, in which the shaft has a plurality of portions formed with ducts made of different materials and/or with different thicknesses.

51. A catheter according to any one of Claims 34 to 50, in which the shaft has an inflation cavity that is in flow communication with the inflation chamber of the

balloon structure, and a thrust wire having a distal end and a proximal end.

52. A catheter according to Claim 51, in which the thrust wire is inside the inflation cavity.

53. A catheter according to any one of Claims 51 to 52, in which the thrust wire extends along the entire length of the shaft.

54. A catheter according to any one of Claims 51 to 53, in which the thrust wire is anchored by its distal end to the balloon structure.

55. A catheter according to any one of Claims 51 to 54, in which the thrust wire is anchored by its distal end to the tip of the catheter.

56. A catheter according to any one of Claims 51 to 55, in which the thrust wire is connected by its proximal end to an inner tube that is present in the shaft.

57. A tip for a catheter such as a catheter for angioplasty or for depositing an endolumenal prosthesis or stent in a duct, for example, a vascular duct, the tip

having a proximal end and an apex end and comprising:

a tubular apex portion disposed in the vicinity of the apex end, and

a proximal connecting tube disposed in the vicinity of the proximal end, in which:

the proximal connecting tube is partially housed with a distal portion thereof inside a proximal portion of the apex tube,

the connecting tube being connected to the apex tube so as to form a cavity which extends without interruption from an opening disposed at the proximal end of the connecting tube to an opening disposed at the apex end of the apex tube,

the connecting tube being suitable for connection to a wall cavity suitable for housing a guide wire, the cavity being provided within a wall which delimits a balloon inflation chamber,

the apex tube being connected proximally in a leaktight manner to a distal opening of a balloon structure for the

leaktight closure thereof.

58. A tip for a catheter such as a catheter for angioplasty or for depositing an endolumenal prosthesis or stent in a duct, for example, a vascular duct, the tip having a proximal end and an apex end and comprising:

an apex tubular portion disposed in the vicinity of the apex end,

a proximal connecting tube disposed in the vicinity of the proximal end, and

a tube for anchoring a thrust wire or rod, also disposed in the vicinity of the proximal end, in which:

the anchoring tube and the proximal connecting tube are arranged at least partially side by side and are housed with respective distal portions inside a proximal portion of the apex tube,

the connecting tube being connected to the apex tube so as to form a cavity which extends without interruption from an opening disposed at the proximal end of the connecting tube to an opening disposed at the apex end of

the apex tube,

the connecting tube being suitable for connection to a wall cavity suitable for housing a guide wire, the cavity being provided within a wall which delimits a balloon inflation chamber,

the anchoring tube being closed distally in a leaktight manner and suitable for connection to a distal opening of a balloon structure for the leaktight closure thereof and for the anchorage of a distal end of a thrust wire.

59. A tip according to Claim 58 in which the anchoring tube, the connecting tube, and the apex tube are welded to form a single body.

60. A tip for a catheter such as a catheter for angioplasty or for depositing an endolumenal prosthesis or stent in a duct, for example, a vascular duct, the tip having a proximal end and an apex end and comprising:

a tubular apex portion disposed in the vicinity of the apex end,

a first proximal connecting tube disposed in the vicinity

of the proximal end, and

a second connecting tube, also disposed in the vicinity of the proximal end, in which:

the first connecting tube and the second connecting tube are arranged at least partially side by side and are housed with respective distal portions inside a proximal portion of the apex tube,

the first and second connecting tubes being connected to the apex tube so as to form cavities which extend without interruption from respective openings disposed at the proximal ends of the connecting tubes to at least one opening disposed at the apex end of the apex tube,

the first connecting tube being suitable for connection to a wall cavity suitable for housing a guide wire, the cavity being provided within a wall which delimits a balloon inflation chamber,

the second connecting tube being suitable for connection to a guide-wire duct suitable for housing a guide wire, the guide-wire duct being disposed inside the balloon structure.

61. A tip according to Claim 60, in which the first and second connecting tubes and the apex tube are welded to form a single body.

62. A method for the production of a tip according to Claims 57 to 61, which provides for the steps of:

- providing an apex tube having a proximal end and a distal end in which an apex opening is provided,

- widening a proximal portion of the apex tube,

- providing a connecting tube suitable for insertion in a wall cavity of a balloon structure, the wall cavity being suitable for housing a guide wire,

- inserting a distal portion of the connecting tube in the widened portion of the apex tube so as to form a continuous cavity between a proximal opening of the connecting tube and the apex opening of the apex tube.

63. A method according to Claim 62, which provides for the further step of:

providing an anchoring tube to be inserted with a distal portion thereof in the apex tube so as to be disposed at least partially beside the connecting tube, the anchoring tube being suitable for anchoring a thrust wire and being suitable for the leaktight closure of a distal opening of an inflation chamber of a balloon structure.

64. A method according to Claim 62, which provides for the further step of:

providing a second connecting tube to be inserted with a distal portion thereof in the apex tube so as to be disposed at least partially beside the first connecting tube, the connecting tube being suitable for forming a second guide-wire cavity between a proximal opening of the second connecting tube and the apex opening of the apex tube, and being suitable for the leaktight closure of a distal opening of an inflation chamber of a balloon structure.

65. A balloon catheter, such as a catheter for angioplasty or for depositing an endolumenal prosthesis or stent in a duct, for example, a vascular duct, comprising:

a shaft in which an inflation cavity is provided, the inflation cavity having a proximal end and a distal end,

an inflatable balloon having a proximal end and a distal end, delimiting an inflation chamber, in which the distal end of the inflation cavity opens in flow communication with the inflation chamber,

a tip which closes the distal end of the balloon in a leaktight manner and has a connecting duct provided with a cavity which has a proximal end and an apex end,

the balloon comprising a wall which has, transverse the longitudinal extent, at any point, an annular cross-section delimited externally by an outer surface which, at least in the intermediate portion, is suitable for coming into contact with an object to be dilated, and internally by an inner surface which delimits an inflation chamber,

in which:

at least one cavity is provided in the wall, and is formed, for its entire extent in the wall of the balloon, within the annular cross-section which delimits the

inflation chamber so as to be disposed between the outer surface and the inner surface, and

the cavity extends without interruptions and/or openings, longitudinally relative to the balloon structure, between the proximal end and the distal end of the balloon.

66. A catheter according to Claim 65, in which a thrust wire is provided in the inflation cavity.

67. A catheter according to Claim 66, in which the thrust wire extends with its distal end as far as the tip of the catheter.

68. A catheter according to Claim 67, in which the distal end of the thrust wire is anchored to the tip.

69. A catheter according to any one of Claims 65 to 68, in which, when the balloon structure is inflated or expanded, the outer surface of the intermediate portion has, in cross-section transverse the longitudinal extent of the balloon structure, uniform curvature around the entire annular extent of the cross-section.

70. A method for the use of a catheter comprising a

balloon structure according to any one of Claims 1 to 69, which provides for the steps of:

- inserting a guide wire in a vessel which is to be operated on,

- fitting a catheter, provided with the balloon structure, on the guide wire, passing the wire through an apex guide-wire aperture, sliding it through a guide-wire wall cavity which, at least for its section corresponding to the extent of the balloon, is disposed in the balloon wall, and causing the wire to emerge from a proximal aperture, relative to the balloon,

- inserting the catheter in the vessel, passing it along the guide wire until the balloon is disposed in the operation zone.

71. A method according to Claim 70, which provides for the further step of:

advancing the catheter on the guide wire by pushing it by means of a thrust wire provided in the catheter body.